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RUEHRC/DEPT OF AGRICULTURE WASHDC
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UNCLAS SECTION 01 OF 02 BEIJING 006201

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HHS FOR OGHA/STEIGER AND PASS TO FDA/LUMPKIN
COMMERCE FOR ITA/HIJIKATA AND CINO
STATE PASS CONSUMER PRODUCTS SAFETY COMMISSION RICH O'BRIEN/INTL PROGRAMS
STATE PASS TO USTR/TIM WINELAND
STATE PASS OMB/INTL AFFAIRS
STATE PASS HOMELAND SECURITY COUNCIL
STATE PASS IMPORT SAFETY WORKING GROUP

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TAGS: TBIO PREL HHS ETRD BEXP CH
SUBJECT: Staffdel Knauer Discusses Drug Export Safety with China Regulators

¶1. (SBU) Summary: In a meeting with Staffdel Knauer on September 3, officials at China's State Food and Drug Administration (SFDA) described a rigorous inspection system for imports and exports of active pharmaceutical ingredients (APIs), but admitted that there is a "fatal" gap in the system between exported APIs and bulk chemicals. SFDA employs 1500 inspectors countrywide who conduct inspections of domestic Chinese drug manufacturers at least once each year. While welcoming more cooperation with the U.S. FDA, SFDA expressed some concerns about a permanent FDA presence in China. In a subsequent meeting with the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), Vice Minister Wei Chuanzhong assured the Staffdel that AQSIQ has developed a good working relationship with counterpart agencies in the United States and will be leading a delegation to Washington on September 9 for consultations on food safety issues. He also pointed out that API exports are all handled by SFDA; AQSIQ only deals with shipments that are identified by importers as bulk chemicals. End summary.

¶2. (SBU) In a meeting at SFDA on September 4, Christopher Knauer, Peter Spencer and Paul Jung of the House Energy and Commerce Committee, met at SFDA with Director General for International Cooperation Xu Youjun and Deputy Director General of Drug Registration Yang Wei. Xu and Yang reported that they were involved in the discussions with U.S. Health and Human Services (HHS) on an MOU that will cover drug quality and safety. They confirmed that the Chinese side had agreed on the date of September 17 next visit to China by the HHS delegation that is negotiating the MOU. Xu pointed to these discussions as an indication of a new level of cooperation between the two agencies.

FDI Presence in China "Difficult"

¶3. (SBU) Mr. Knauer commented on the increasing globalization of drug manufacturing and how difficult it has become for FDA to inspect all of the overseas plants that export to the United States. He wondered if having a permanent FDA presence in China would help address this problem. In response, DG Xu suggested that a permanent FDA presence in China would be "difficult" and "may not be very practical." She said China is committed to improving its own inspection system and noted that China has established a working group on product safety that involves seven ministries and has

launched a new rectification campaign that aims to strengthen relevant laws and regulations. She suggested that that the Good Manufacturing Practices (GMP) certification should be a global standard and that SFDA, which currently has 1500 inspectors, has already certified 4,682 firms in China.

¶4. (SBU) DDG Yang argued that both SFDA and FDA share the same vision of ensuring safety and identified the API issue as an area deserving special attention in the bilateral discussions. Yang noted that as of 2004, all APIs require SFDA certification. Inspections of API manufacturers are conducted on a yearly basis, with at least 25 percent of the inspections being unannounced. Imported APIs must be inspected at the port and every lot must be inspected separately. Yang confirmed that SFDA also conducts post-surveillance and post-approval inspections. While most inspections are done by provincial SFDA inspectors, all inspections of "high risk" materials are organized by the central government's SFDA. The four categories of "high risk" drug products are: 1) biological products (e.g., blood, vaccines), 2) large volume injectables, 3) traditional Chinese medicine injectables, and 4) recombinant biochemical products.

APIs a "Fatal" Gap

¶5. (SBU) Yang reported that for APIs, SFDA tests every batch. He noted that the United States does not currently have such a system and urged the FDA to strengthen its inspection of API imports. In this effort, China is willing to provide a list of registered API exporters. He pointed out that the critical "fatal" gap in the current arrangement is that some API exports to the United States are labeled as bulk chemicals. As such, they can therefore elude SFDA oversight.

¶6. (SBU) In a follow-on meeting with AQSIQ, Vice Minister Wei Chuanzhong told the Staffdel that he had previously met with Staffdel Nelson and Representatives Kirk and Larson (see septels). Reviewing points shared with the previous visitors, VM Wei noted that he will be leading a delegation to the United States on September 9 that will focus on establishing a cooperative framework with FDA, HHS, the U.S. Department of Agriculture and the Consumer Product Safety Commission. He reported that according to his agency's figures, Chinese exports to the United States from 2004 to 2006 had consistently scored above 99 percent in terms of quality. He complained that any problems were simply isolated incidents and that the media had distorted the true picture. Wei maintained that AQSIQ, especially at the local level, has developed a strong working relationship with FDA.

¶7. (SBU) Mr. Spencer asked Wei how AQSIQ and SFDA work together on APIs exports. Wei said SFDA handles all matters related to pharmaceutical products, including APIs. AQSIQ has no role with regard to bulk pharmaceuticals; only bulk chemicals products need AQSIQ approval. Wei confirmed that there is no way to tell the difference - it is the importer who states what the chemical will be used for and it can thereby be classified as an industrial, food or pharmaceutical product.

¶8. (U) This report was cleared by the delegation.

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